

Notice of Allowability

Application No.

10/500,672

Examiner

Chih-Min Kam

Applicant(s)

BEDNAREK, MARIA A.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/18/07.
2. ☒ The allowed claim(s) is/are 29-41.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Status of the Claims

1. Claims 29-41 are pending.

Applicant's amendments filed May 1 and May 18, 2007 are acknowledged. Applicants' response has been fully considered. Claims 29, 33 and 40 have been amended. Therefore, claims 29-41 are examined.

2. The Sequence Listing filed June 14, 2007 is acknowledged, and CRF has been entered.

Withdrawn Claim Objections

3. The previous objection to claim 39 is withdrawn in view of applicant's amendment of the claims in the amendment filed May 1, 2007.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 29-33, 35-37 and 40-41 under 35 U.S.C.112, first, paragraph, written description, is withdrawn in view of applicant's amendment of the claim, and applicant's response at pages 6-7 in the amendment filed May 1, 2007.
5. The previous rejection of claims 33, 38, 40 and 41 under 35 U.S.C.112, second paragraph, is withdrawn in view of applicant's amendment of the claim, and applicant's response at pages 7-8 in the amendment filed May 1, 2007.

Withdrawn Claim Rejections - Obviousness Type Double Patenting

5. The previous rejection of claims 29-32, 34-38, 40 and 41 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-30, 34-37 and 42-43 of co-pending Application No. 10/182,509 (Now U.S. Patent 7,220,720), is withdrawn in view of applicant's submission of a terminal disclaimer in the amendment filed May 18, 2007.

Examiner's Amendment

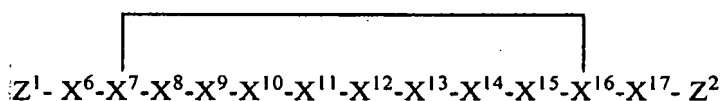
An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Catherine Fitch on June 12, 2007.

Examiner's Amendment to the Claims:

Claims 29-31, 35 and 40 have been amended as follows:

Claim 29 (Currently amended): A peptide ~~having~~ consisting of the structure:



wherein X^6 is selected from the group consisting of: D-arginine, D-alanine, D-norleucine, D- α -aminobutyric acid, D-valine, D-leucine, D-isoleucine, D-proline, D-methionine, D-phenylalanine, D-asparagine, D-glutamine, D-serine, D-threonine, D-glutamic acid, D-aspartic acid, D-lysine, D-histidine, D-tryptophan, D-tyrosine, D-cyclohexylalanine, D-(2')naphthylalanine, D-ornithine, D-homoarginine, D-nitroarginine, D-norarginine, and D-citrulline ~~and 5-guanidinopropionic acid~~,

X^7 is cysteine,

X^8 is either methionine, norleucine, or N-methyl norleucine,

X^9 is leucine,

X^{10} is either ~~is either~~ asparagine, glutamine, leucine, isoleucine, valine, norleucine, cyclohexylalanine, phenylalanine, (2')-naphthylalanine, tyrosine, histidine, tryptophan, lysine, serine, threonine, methionine, or citrulline,

X^{11} is arginine,

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 X^{12} is valine, X^{13} is phenylalanine, (2')naphthylalanine, p-fluoro-phenylalanine, tyrosine, or cyclohexylalanine, X^{14} is arginine or alanine, X^{15} is either proline or sarcosine, X^{16} is cysteine or D-cysteine, X^{17} is an optionally present amino acid that, if present, is either tryptophan or tyrosine, Z^1 is an optionally present protecting group that, if present, is covalently joined to the N-terminal amino group, Z^2 is an optionally present protecting group that, if present, is covalently joined to the C-terminal carboxy group, and

wherein said peptide optionally contains a detectable label, or a pharmaceutically acceptable salt of said peptide.

Claim 30 (Currently amended): The peptide of claim 29, wherein said detectable label is ~~selected from the group consisting of:~~ a luminescent label, an enzymatic label, ~~and~~ or a radiolabel.

Claim 31 (Currently amended): The peptide of claim ~~30~~ 29, wherein said detectable label is not present.

Claim 35 (Currently amended): The peptide of claim 33, wherein said peptide is not substituted with a ~~detectable label~~ radiolabel.

Claim 40 (Currently amended): A method of screening for a compound able to bind MCH-1R comprising the step of measuring the ability of said compound to inhibit binding of a ~~detectably-labeled~~ peptide of claim 29 to MCH-1R, ~~by measuring the change in detectable label wherein said compound that inhibits binding of the peptide to MCH-1R is identified as able to~~ bind MCH-1R.

The following is an Examiner's Statement of Reasons for Allowance: The following references appear the closest art to the claimed invention. Maratos-Flier *et al.* (U. S. Patent 5,849,708) disclose MCH agonists having the formula of $R^1-R^2-R^3-R^4-R^5-R^6-R^7-R^8-R^9-R^{10}-R^{11}-R^{12}-R^{13}-R^{14}-R^{15}-R^{16}-R^{17}-R^{18}-R^{19}$ (SEQ ID NO:3), among variable substitutions at each position,

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R¹, R², R³, R⁴, R⁵ can be deleted; R⁶ can be Arg, a conserved amino acid substitution, a D amino acid or deleted; R⁷ can be Cys or an amino acid; R⁸ can be Met, a conserved amino acid substitution or Cys; R⁹ can be Leu, Val or a conserved amino acid substitution; R¹⁰ can be Gly or a conserved amino acid substitution (e.g., Ala, D-Ala, Pro, D-Pro, β -Ala); R¹¹ can be Arg or a conserved amino acid substitution; R¹² can be Val or a conserved amino acid substitution; R¹³ can be Tyr or a conserved amino acid substitution; R¹⁴ can be Arg or a conserved amino acid substitution; R¹⁵ can be Pro, a conserved amino acid substitution or Cys; R¹⁶ can be Cys or an amino acid; R¹⁷ can be Trp, a conserved amino acid substitution, an aromatic amino acid or Cys; R¹⁸ can be Gln, Glu or Trp, a conserved amino acid substitution or deleted; R¹⁹ can be Val, a conserved amino acid substitution or deleted; if R⁷ is Cys, then R¹⁶ is Cys, and the disulfide bond forms between R⁷ and R¹⁶; the preferred embodiments are: R¹² is Val, R¹³ is Tyr, R¹⁴ is Arg, R¹⁵ is Pro, R¹⁶ is Cys, R¹⁷ is Trp, the disulfide bond forms between R⁷ and R¹⁶, the agonist is for any or all residues deleted between R¹ and R⁶, and between R¹⁸ and R¹⁹; one preferred embodiment is MCH(6-17). The patent also teaches MCH antagonists having the formula of R¹-R²-R³-R⁴-R⁵-R⁶-R⁷-R⁸-R⁹-R¹⁰-R¹¹-R¹²-R¹³-R¹⁴-R¹⁵-R¹⁶-R¹⁷-R¹⁸-R¹⁹ (SEQ ID NO:3) with R¹² being any amino acid other than Val, or other than a conserved amino acid replacement; one preferred embodiment is MCH(6-16). However, Maratos-Flier *et al.* do not teach the MCH agonist or antagonist is MCH(6-16) or MCH(6-17) with R¹⁰ being Asn, Gln, Leu, Ile, Val, Nle, cyclohexylalanine, Phe, (2')Naphthylalanine, Tyr, His, Trp, Lys, Ser, Thr, Met or Cit. Bednarek (U. S. patent 7,220,720) teaches truncated MCH analogs having the structure of Z¹-X⁶-cyclo(X⁷-X⁸-X⁹-X¹⁰-X¹¹-X¹²-X¹³-X¹⁴-X¹⁵-X¹⁶)-Z² such as SEQ ID NO: 48, 49, 51 and 52 which are encompassed by the claimed invention, and a terminal disclaimer has been filed over the patent. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

June 14, 2007